

REMARKS

This Amendment is in reply to the Office Action mailed September 7, 2005. Applicants have reviewed the Office Action and have the following comments.

Rejection Pursuant to 35 U.S.C. §112(2)

The Office Action has rejected claim 30 as being allegedly indefinite as being dependent from cancelled claim 17. Applicants regret the oversight and have corrected claim 30 by ensuring that the claim no longer depends from claim 17. Applicants regret any inconvenience caused by this oversight.

Rejection Pursuant to 35 U.S.C. §103(a)

The Office Action has rejected claims 16, 18-22 and 30 as being allegedly obvious over U.S. Patent Application 2002/0040015, to Miller et al., in view of Wheeler et al., Eur. J. Ophthal. 9:S17-S21 (1999). The Office Action characterizes Miller et al. as disclosing a method and composition for treatment of the eye having an ocular condition characterized by unwanted choroidal neovascularization comprising administering to said eye an anti-angiogenic compound and a neuroprotective compound that represses apoptosis in cells or tissue surrounding the treatment area. Further, Wheeler is cited as teaching that brimonidine is an alpha 2 agonist compound that is neuroprotective in animal models of retinal and optic nerve injury. Therefore, the Office Action concludes, it would have been obvious to one of skill in the art on file filing date to perform the method of Miller and substitute brimonidine as the neuroprotective agent. Applicants respectfully

traverse both the characterization of the teachings of the cited references and this rejection for the following reasons.

The present patent application was filed on October 30, 2001 and claimed priority to provisional patent application 60/244,850, filed November 1, 2000. The disclosure of the provisional application (including the claims thereof) included methods of using a neuroprotectant in conjunction with photodynamic therapy (PDT); exemplary neuroprotectant compounds named in the provisional specification included NGF, PEDF, CNTF, BDNF, brimonidine and memantine.

Miller (U.S. Serial No. 09/780,142) was filed February 9, 2001 as a non-provisional application claiming priority to provisional application 60/181,641, filed February 10, 2000. This provisional application included some disclosure of the use of PDT with certain anti-angiogenic agents, with targeted photosensitizers, and with an "apoptosis-inducing factor". However, unlike the later non-provisional application, there is no disclosure in the provisional application of the use of PDT with anti-apoptosis agents, nor is there any disclosure in either the Miller provisional or non-provisional application of the administration of neuroprotectants in conjunction with PDT. Compounds such as NGF, PEDF, CNTF, BDNF are not named in the provisional application. Applicants hereby submit a copy of the Miller 60/181,641 provisional application for the Examiner's convenience.

Therefore, Miller's disclosure of apoptosis-repressing factors, which has a date of constructive reduction to practice of February 9, 2001 is not prior art to the pending claims of the present patent application, which have a date of constructive reduction to practice of November 1, 2000.

As such, the prior Office Actions' dependence upon such disclosure by Miller in an attempt to make out a case of obviousness is respectfully submitted to be improper.

The presently pending claims are drawn to methods of protecting ocular neurons from damage during PDT treatment comprising the administration of a neuroprotectant amount of the alpha 2 agonist brimonidine.

Nothing in the combination of the Miller provisional patent (disclosing apoptosis-inducing agents, anti-angiogenic agents and targeted photosensitizers) application 60/181,641, with the Wheeler paper (disclosing that brimonidine is neuroprotectant) would suggest or lead the person of ordinary skill in the art to the present invention. Such suggestion can therefore only come from the present patent specification, which is impermissible hindsight reconstruction.

For these reasons the Applicants respectfully request reconsideration and withdrawal of the present rejection.

Rejection Pursuant to Non-Statutory Obviousness-type Double Patenting

Claims 16, 18-22 and 30 were rejected as being allegedly unpatentable due to obviousness type double patenting over claims 1-12 of US Patent No. 5,856,329 (the '329 patent) in light of Miller et al., US 2002/0040015 A1. Applicants respectfully traverse this rejection, for the following reasons.

The Examiner argues what claims 1-12 of the '329 teach. (See page 5 of the September 7, 2005 Office Action). Respectfully, this is not the proper inquiry in a non-statutory obviousness-type double patenting rejection. Rather, the question in such an inquiry is whether the claims of the earlier co-owned patent or

application (in this case the '329 patent) are drawn to an invention that is not patentably distinct from the claims of the later filed application. See e.g., Manual of Patent Examining Procedure § 804(B)(1) at page 800-21 (Rev.3 August 2005) (hereinafter "MPEP"). Moreover, in making such a determination, the disclosure of the patent cannot be used as prior art. See *id.*

Further, the only consideration in an obviousness-type double patenting rejection is whether the claims of the newer patent application are merely obvious variations of the claims of the prior patent or application. It is therefore improper to reject a patent claim in a "prior art" rejection, for example, in view of a secondary reference (such as Miller in this case). This is because only the claims of the two commonly owned patent applications (or patent and application) may be compared for obviousness. See MPEP §804 III at 800-28 - 800-29.

The present claims are directed to methods of protecting ocular neural tissue from damage caused by photodynamic therapy (PDT) treatment. The Examiner has identified no claim of the '329 patent that is drawn to a patentably indistinct invention from the claimed methods of protecting tissue from damage due to PDT. The Examiner has used both the present specification, and a prior art reference to attempt to demonstrate double patenting. See Office Action pages 9 and 10. Neither are permissible actions for such purpose.

Finally, as stated above, Miller is not available prior art for the proposition that apoptosis-repressing compounds can be administered in conjunction with PDT. While Miller discloses PDT, nothing in Miller suggests the use of a neuroprotectant in conjunction with PDT. And even assuming, solely for the sake of argument, that the claims of the '329 patent encompass and

dominate the present claims, there is no mention of PDT in the '329 patent, and thus method claims drawn to methods of improving PDT are patentably distinct over such claims.

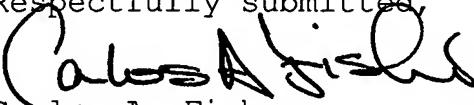
For these reasons the Applicants respectfully request reconsideration and withdrawal of the present rejections.

CONCLUSION

For the reasons given above, the claims are now thought to be in condition for allowance, and a Notice to that effect is earnestly sought.

No fee is thought due in connection with this communication. However, if Applicants are in error with regard to this point, please use Deposit Account 01-0885 for the payment of any such fee now due, or to credit any overpayment.

Respectfully submitted,


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